SIERRA SCIENTIFIC INSTRUMENTS

"Innovations in diagnostic technology"

510(k) Summary

MAY 19 2009

Identification:

Date:	April 3rd, 2009
Applicant's/Owner's Name:	Sierra Scientific Instruments, Inc.
Phone number:	310. 641.8492
Fax number:	310. 872.5558
Submission Contact person:	Eric S. Finkelman
Phone number:	310.641.8492
Fax number:	310.872.5558
Manufacturing site address:	Sierra Scientific Instruments, Inc. 5757 West Century Boulevard Suite 660 Los Angeles, CA 90045
Device Trade Name:	Gastrointestinal Motility System (Electrical)
Proprietary Name:	ManoScan Motility with Impedance Visualization System
Device classification:	Class II
Panel / Regulation Number:	876.1725
Product Code	FFX
Establishment registration number:	3005344223

Substantial equivalence claimed to:

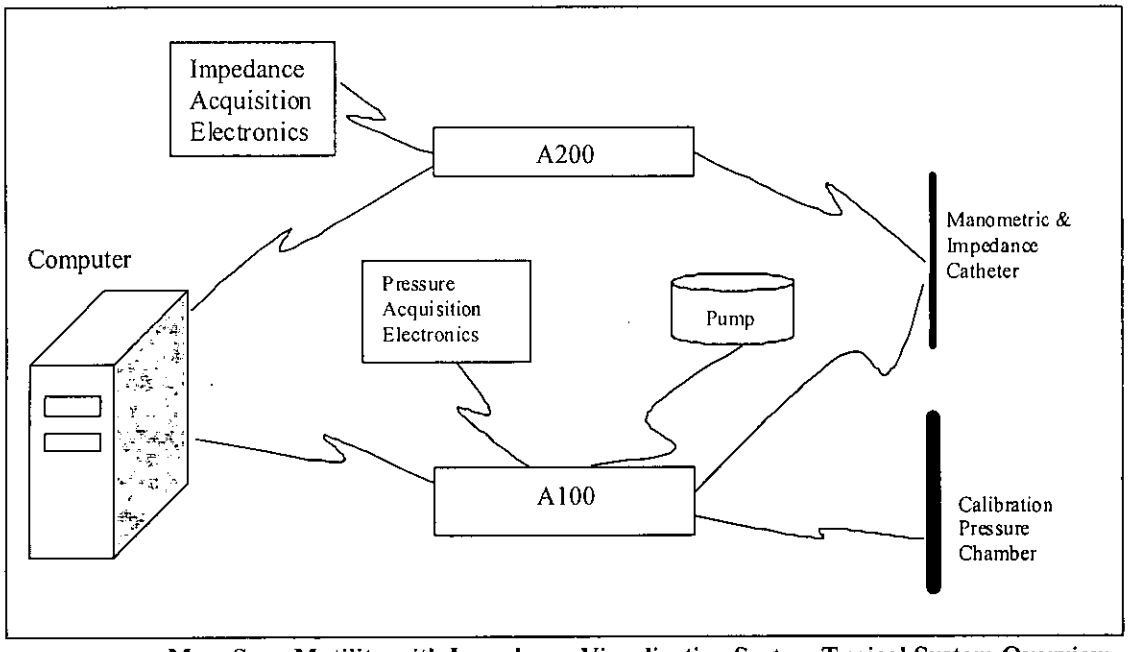
1. K031169 - Sierra Scientific Instruments, Inc. –Motility Visualization System; ManoScan
2. K984444 / K012232 - Sandhill Scientific Instruments, Inc - InSight Motility Visualization System
3. K052338 - Medical Measurement Systems B.V.- Solar GI High Resolution Manometry with Impedance System

Description:

The ManoScan Motility with Impedance Visualization System is used to acquire gastrointestinal tract data in order to present a high-resolution mapping of pressures with Impedance levels within tubular organs. It includes the ability to acquire, display and replay video data captured from within the gastrointestinal tract organs. The ManoScan Motility with Impedance Visualization can be used with either or both of the video with Impedance data capture features disabled.

The System is used in a medical clinical setting to sense pressure and Impedance levels, acquire and store the corresponding data and enable viewing or analyzing in real time or anytime after the data is acquired and stored. Accordingly, the System provides visualization and analysis tools that can be used for evaluation of the data and analytic diagnosis.

The system includes a catheter probe that can be configured with a variety of pressure sensing element with Impedance sensor channels. During the clinical procedure, the catheter is inserted transnasally, transorally or via rectal intubation and pressure with Impedance levels from inside the gastrointestinal tract are monitored. Data collection can include acquisition of data from different segments of the GI tract, including the pharynx, upper esophageal sphincter (UES), esophagus, lower esophageal sphincter (LES), stomach, sphincter of oddi, small bowel, colon, duodenum and anorectal area. Real-time data is sampled from each sensing element and sensing channel via the interface electronics and made available to the software during each sample period. The software displays the data in real-time to support the clinical procedure.



ManoScan Motility with Impedance Visualization System Typical System Overview

The software also supports operational utility functions such as providing the user an interface for operating the pressure calibration pump. It obtains the catheter pressure sensor and calibration chamber data during the calibration process and determines the correction factors to be used in subsequent data collection.

The ManoScan Motility with Impedance Visualization system supports physician diagnosis and analysis by means of a playback / review function, which replays a stored session using previously recorded pressure, impedance and video data instead of real-time data. This analysis and diagnosis function is enabled through the presentation of pressure levels, gastrointestinal tract bolus presence, impedance levels and video. During review and analysis, the impedance and video can be reviewed and analyzed in conjunction with pressure profiles and associated estimated parameters such as LES location, LES resting pressure, LES relaxation, LES residual pressure, pressure inversion point (PIP) location, UES pressure, and esophageal motility such as amplitude duration and velocity.

Product Functions

The primary ManoScan Motility with Impedance Visualization functions are:

- Calibrate the pressure sensors
- Provide user interface displays, prompts, and controls
- Collect pressure, impedance and video data
- Display, store and replay collected data
- Provide analysis and diagnostic tools via software application

Intended use:

The ManoScan Motility with Impedance Visualization obtains a high resolution mapping of pressures with Impedance levels within organs of the human gastrointestinal tract. These include the pharynx, upper esophageal sphincter (UES), esophagus, lower esophageal sphincter (LES), stomach, sphincter of oddi, small bowel, colon, duodenum and anorectal organs. It is used in a medical clinical setting to acquire pressures, impedance levels and video, to aid in documenting and diagnosing motility, digestive tract and swallowing disorders. The system also provides visualization and analysis tools and reports that can be viewed for diagnostic purposes by appropriately trained medical personnel.

The system includes a catheter probe that can be configured with a variety of pressure sensing elements with Impedance sensor channels. During the clinical procedure, the catheter is inserted transnasally, transorally or via rectal intubation and pressure with Impedance levels from inside the gastrointestinal tract are monitored

Summary of Technological Characteristics:

The ManoScan Motility with Impedance Visualization System catheter represents a modification to the predicate Sierra Scientific Instruments, Inc. Motility Visualization System; ManoScan pressure sensing catheter. The primary difference is the addition of cylindrical gold conductive rings that create impedance measurement electrodes, when impedance is enabled. Configurations of the subject device will also vary the number of pressure sensors (typically 8 - 36 for the predicate device). The ManoScan Motility with Impedance Visualization System uses a multiplexing scheme to minimize the number of electrical conductors.

The ManoScan Motility with Impedance Visualization System system includes separate modules for acquisition of the impedance and pressure data. Both acquisition modules communicate with the data acquisition software via a standard computer platform. Video is captured via standard video capture devices and synchronized within the software application.

The user interface is via touch screen display, keyboard and mouse and the use of a hard drive that allows recording and play back of the data. By providing more data, the system gives a more complete pressure, impedance and video data set of the segment of the gastrointestinal tract being investigated. The system can also be used if there are inactive sensors or channels and can be configured with different combinations of the pressure, impedance and video capabilities.

Substantial Equivalence - Summary of Technical Similarities / Differences with Predicate Devices:

As mentioned above, the ManoScan Motility with Impedance Visualization System hardware architecture is identical to the predicate Motility Visualization System; ManoScan device with the only system difference being that the ManoScan Motility with Impedance Visualization System device includes separate modules for auxiliary data like impedance and video. This modules are designed to communicate directly with the software, along with the pressure data acquisition module. As with the predicate devices, the ManoScan Motility with Impedance Visualization System includes a communication link between the data acquisition modules and a computer which hosts the acquisition and analysis software.

The ManoScan Motility with Impedance Visualization System catheter uses the same proprietary capacitive tactile pressure sensor technology utilized in the predicate Motility Visualization System; ManoScan device to provide circumferential pressure sensing along the active length of the catheter. Pressure sensors are presented in an array similar to the predicate Motility Visualization System; ManoScan device, with certain configurations of the ManoScan Motility with Impedance Visualization System device providing higher density pressure arrays to provide greater measurement resolution.

Additionally, the ManoScan Motility with Impedance Visualization System catheter includes impedance electrodes which are not present in the predicate Motility Visualization System; ManoScan device but have the same technological characteristics as the predicate catheters provided with the InSight and Solar GI devices referenced. More specifically, the ManoScan Motility with Impedance Visualization System catheter includes impedance electrodes which are integrated into the catheter via a core catheter construction that is identical to the predicate Motility Motility with Impedance Visualization System; ManoScan device and are presented as conductive rings. Each pair of rings creates an impedance channel. This is identical in technology approach as the predicate Insight and Solar GI devices. Aside from the core catheter construction and the pressure sensing technology utilized in the applicant ManoScan, which is identical to the predicate Motility Visualization System; ManoScan device, the primary technology differences with the predicate Insight and Solar GI impedance devices is the impedance electrode material, the number of impedance electrodes and channels as well as the relative location of the impedance electrodes. As compared to these predicate devices, the ManoScan Motility with Impedance Visualization System device uses an impedance electrode ring design which provides equivalent or better impedance measurement effectiveness and enables catheter configurations and data acquisition modules that support a higher number of pressure with Impedance sensors to improve pressure with Impedance signal measurement coverage and resolution.

The ManoScan Motility with Impedance Visualization System device supports video data capture and analysis with similar technological characteristics as the predicate Solar GI device.

Finally, the ManoScan Motility with Impedance Visualization System is designed and certified to be in accordance with the same applicable standards and non-clinical tests as the predicate Motility Visualization System; ManoScan pressure measurement device, and the Insight and Solar GI pressure with Impedance devices. Additionally, the ManoScan Motility with Impedance Visualization System is designed with a target customer base similar to the predicate ManoScan, Insight and Solar GI devices.

Summary of Hardware / Software Components

Acquisition Hardware – This subsystem, manufactured by Sierra Scientific Instruments, Inc., includes data acquisition modules that are used for power control, calibration control and acquiring and processing the electrical, video, pressure with Impedance and auxiliary data signals while providing the necessary electrical isolation for safety.

Catheter Assembly including Sensors and Electrodes – the sensors and electrodes included in the catheter assembly are used for generating data signals in response to physiological events to which they are exposed. They are manufactured by Sierra Scientific Instruments, Inc. The catheter, sensors and electrodes are assembled and tested in such a manner as to meet or exceed the necessary patient safety requirements and meet or exceed the performance characteristics of the predicate devices.

Acquisition and Analysis Software – the software controls the calibration procedure, clinical procedure protocol, and provides analysis tools while providing visualization tools that can be used during the procedure, analysis or in generating reports. The software includes warnings and visual indicators that alert users if product performance or operating conditions are not meeting performance requirements. The software is developed by Sierra Scientific Instruments, Inc. and is verified and validated to ensure the product meets or exceeds the performance characteristics of the predicate devices.

Applicable Standards and Non-Clinical Testing

In accordance with Sierra Scientifics Instruments' Product Realization procedures, the ManoScan Motility with Impedance Visualization System has been designed and verified to meet the appropriate elements of the following standards:

IEC 60601-1:1988 + A1:1991 + A2:1995
EN 60601-1-2 AND IEC 60601-1-2
ISO 10993

Certification to the above standards is achieved through a combination of internal design documentation and external lab testing against approved protocols. Specifically, the above confirm adherence to the appropriate levels of product safety, emissions, voltage immunization and biocompatibility.

Bench-top Verification Tests have been performed to verify product performance meets or exceeds performance of the predicate devices. This has included pressure with Impedance accuracy, noise and repeatability measurement tests performed as part of the Design Verification and Validation process.

No formal clinical testing has been performed, nor is any believed to be necessary.

Safety and Potential Adverse Health Effects

The ManoScan Motility with Impedance Visualization System has been designed to completely eliminate or mitigate all known health hazards associated with use of the device. Health hazard risk reduction has been achieved through application of a rigorous risk management program that is included as part of the Sierra Scientific Instruments, Inc. design process and documents as part of the device Safety Risk Analysis. One or more of the following was used to mitigate the health hazards identified by the risk management program:

1. Design Verification and Validation Testing and Certification to Applicable Standards
2. Material / Product Conformance Inspection and Acceptance Testing Criteria

3. Detection of hazardous or non-conforming conditions via software and alerting the user through alarms and visual indicators.
4. Identification of health hazard conditions and related cautions in the instruction manual and other device labeling
5. Training of qualified personnel to perform procedures and interpret results.

Sierra Scientific Instruments, Inc believes that the ManoScan Motility with Impedance Visualization System is a safe and effective device and has been proven to meet or exceed the performance and safety levels of the legally marketed Motility Visualization System; ManoScan, Insight and Solar GI predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2009

Sierra Scientific Instruments, Inc.
c/o Mr. Jeffrey D. Rongero
Senior Project Engineer
UL Health Sciences
Underwriters Laboratories, Inc.
12 Laboratory Drive
RESEARCH TRIANGLE PARK NC 27709

Re: K091070
Trade/Device Name: ManoScan Motility with Impedance Visualization System
Regulation Number: 21 CFR §876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: II
Product Code: FFX
Dated: May 1, 2009
Received: May 4, 2009

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

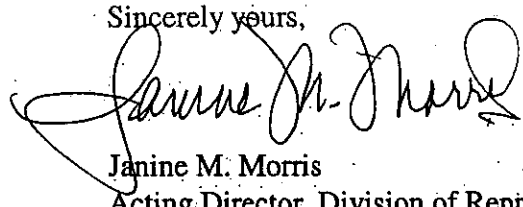
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: ManoScan Motility with Impedance Visualization System

Indications For Use:

The ManoScan Motility with Impedance Visualization System obtains a high resolution mapping of pressures and impedance levels within organs of the human gastrointestinal tract. These include the pharynx, upper esophageal sphincter (UES), esophagus, lower esophageal sphincter (LES), stomach, sphincter of oddi, small bowel, colon, duodenum and anorectal organs. It is used in a medical clinical setting to acquire pressures, impedance levels and video and store the corresponding data. The system also provides visualization and analysis tools and information. The real time data as well as the analysis information can be viewed for diagnostic and analysis purposes with an intention of assisting in the diagnosis and evaluation of gastrointestinal and swallowing disorders. The device is intended for use by gastroenterologists, surgeons and medically trained personnel.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091070